PD7 McCann Opp Exh 07



Agenda

Topics:

- Review select Pharmacists specific to district/market with GFD opportunities
- Review controlled substances validation procedures
- Case Studies
- Review controlled substance prescription examples with the pharmacist



Intended Outcomes:

- Identify opportunities for improvement specific to a pharmacist by reviewing potential issues in controlled substance dispensing
- Reiterate the GFD and TD GFD Validation Procedure



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Why are we doing this?

- To better assist supervision in evaluating overall GFD and controlled substance dispensing by reviewing prescriptions filled by select pharmacists.
- To provide a framework for the RXS to review controlled substance dispensing in our stores.
- This process is intended to assist pharmacists and assess, as well as support, their exercise of professional judgment while carrying out their corresponding responsibility under the law.



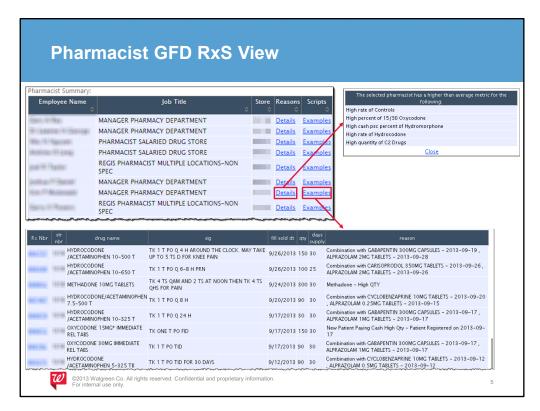
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Pharmacist GFD Overview

- Pharmacist GFD Tool:
 - RxS can view pharmacists that have been selected in their district
 - Prescription data is refreshed monthly
 - Pharmacist data is refreshed quarterly
- Pharmacists were selected based on dispensing patterns in 5 or more categories:
 - Alprazolam, Carisoprodol, Hydrocodone, Hydromorphone, Methadone, Oxycodone, all CII, and all CIII - CV
- The report contains prescriptions that can be used as GFD coaching opportunities



• RxS receives a monthly e-mail notifying them of updated data



- Pathway: Tools > GFD Opportunities > Pharmacist GFD
- This tool was designed to provide a framework for the RXS to review controlled substance dispensing in our stores.
- This process is intended to assist pharmacists and assess, as well support, their exercise of professional judgment while carrying out their corresponding responsibility under the law.
- · Authenticator ID based views:
 - EPDs can view a operation
 - MPDs can view a market
 - RxS can view a district

On a supervision visit, the RXS/DM can pull up real examples to pull to look for documentation or to go over with the pharmacists to reinforce GFD.



Review: Validation Process for Controlled Substances

Pharmacists should consider all available resources that can assist them in determining the appropriateness of filling a controlled substance prescription. This may include:

- Referencing the state Prescription Drug Monitoring Program website (in states where this is available)
- · Reviewing the patient's profile
- · Conversation with patient or caregiver
- Considering information from other pharmacists in the community (if indicated).
- · Identifying prescriber trends
- · Conversation with prescriber or clinical staff as needed

There are 3 key lenses through which a prescription should be evaluated when a pharmacist is presented with a controlled substance prescription.

- 1. Prescriber
- 2. Individual/Patient
- 3. Prescription



Prescriber Considerations

- Prescription is written by a prescriber located outside of the pharmacy's trade area.
- Prescriber routinely prescribes large number (or percentage) of prescriptions for controlled substances relative to prescriptions for noncontrolled substances.
- Prescriber prescribes the same medication, with the same directions, for the same quantity for a large number of individuals.
- 4. Prescriber provides the same diagnosis for the majority of individuals.
- 5. Prescriber commonly writes narcotic prescriptions for individuals between 18-35 years old, especially chronic therapy.
- Knowledge that prescriber operates on a "cash only" basis does not accept insurance.



- 1.
- Is the individual traveling to visit this prescriber? If so, why?
- Is the prescriber engaged in a specialty practice that is not readily available locally?
- Is the prescriber part of a major medical institution or regional center of excellence where individuals would typically travel to seek specialized care (ex. Mayo Clinic)?
- It is not uncommon for individuals to travel outside of their community to obtain legitimate medical care and services that are not readily available from local prescribers, or to receive care at nationally or regionally renowned medical institutions / centers of excellence particularly in the case of rare or life-threatening diseases.
- Drug abusers are known to sometimes travel outside of their local area, and in many cases across multiple states, to obtain prescriptions for controlled substances from prescribers who are willing to write them for illegitimate purposes.
- 2.
- Is the prescriber Board Certified in a specialty that typically utilizes the types and quantities of controlled substances being prescribed (examples: Pain Management, Oncology, Orthopedics, etc.)?
- Are the controlled substances being prescribed consistent with the diseases or conditions that would be treated by the prescriber's area of
 practice? Does the prescriber also write for non-controlled substances that are consistent with their area of practice? Is the prescriber's
 prescribing pattern similar to that of other prescribers (within same specialty) in the community?
- Is the age of the individual receiving controlled substance consistent with the prescriber's area of practice (i.e., is a pediatrician writing for a 50 year-old individual)?
- Are the controlled drugs prescribed in the identical or same chemical class? (i.e., opiates)
- In the usual course of legitimate medical practice, similar prescribing patterns are often observed among prescribers in a given specialty or area of practice. A common trend observed in established cases of abuse includes the disproportionate prescribing of controlled substances by the prescriber when compared to the prescribing habits of other prescribers in the same specialty or area of practice.
- There have been established cases of illegitimate prescribing of controlled substances where the prescriber's area of practice has not been consistent with either the drugs being prescribed or the age of the individual being treated (example: a pediatrician prescribing narcotic analgesics for adults).
- · Are the controlled substance quantities and directions being prescribed consistent with the diseases or conditions for each individual?
- Are most of the prescriptions written for the same combination of medications?
- 3.
- · Are the controlled substance quantities and directions being prescribed consistent with the diseases or conditions for each individual?
- Are most of the prescriptions written for the same combination of medications?
- · This is a prescribing behavior that has been observed in documented "pill mill" cases. It is very questionable that in the usual course of

- practice, most or all individuals would require the exact same combination of controlled substances and doses as part of a legitimate medical regimen.
- Prescribing behavior in which treatment is not individualized may be an indicator that a proper prescriber-patient relationship does not exist.

4.

- Does the prescriber practice in a very narrow, specialize area of medicine?
- Is it plausible that all individuals have the same diagnosis? Does it appear unrealistic?
- The lack of individualized treatment for these individuals could be indicative of improper prescribing practices and an indication that the prescriptions were not written for a legitimate medical purpose.

5.

- Does the prescriber specialize in a particular field that is more applicable to this age group, for example Sports Medicine?
- Are individuals in this age range receiving short or long-term narcotic therapy?
- Is the prescriber located in an area with a younger population (e.g., near a college campus)?
- While drug abuse can occur at any age, there tends to be a higher prevalence of abuse within this age range.
- Outside of the oncology or hospice setting, there is generally a low incidence rate of individuals in this age range requiring long-term opiate therapy. Diagnosis and treatment plan are key pieces of information to obtain when evaluating appropriateness.

6.

• There have been documented cases of "pill mills" operating on a cash-only basis. While operating on a cash-only basis does not necessarily imply that the prescriber is running a "pill mill" it is a red flag that should be considered in light all any other red flags that may be present when evaluating a prescription.

Individual/Patient Considerations

- 1. Individual pays cash, or insists paying cash for controlled substances even though insurance is on file.
- 2. Evidence of "doctor shopping" exists.
- 3. Evidence of "pharmacy shopping" exists.
- Individual resides outside of the trade area of your pharmacy (cannot be reasonably explained).
- The individual's statement and conduct or behavior suggest abuse of controlled substances.
- Individual routinely attempts to obtain an early refill on controlled substances.
- 7. Individuals have suspicious relationships with each other.



1.

4.

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• It is a well-established trend that individuals seeking to illegitimately obtain controlled substances will often attempt to pay cash for the prescriptions. This may be due in part to their belief that their behavior will go undetected if submitting claims to the prescription plan is circumvented.

When reviewing the individual profile and/or state PMP site (where available), has the individual received prescriptions for controlled

- substances in the same therapeutic class from more than one prescriber? If yes, are the prescribers associated as part of the same group practice, or from different practices?
- Is the individual receiving controlled substances from multiple prescribers during the same (i.e. overlapping) period of time?
 Prescription drug abusers will often attempt to obtain controlled substances from multiple prescribers during adjacent or overlapping periods of time. The prescribers being visited are typically not part of the same group practice, and many times may be located in different communities.
- It is not uncommon in large group practices for individuals to see different prescribers in the group practice at different points in time.

 Therefore, particular attention should be paid to the time periods in which the prescriptions have been filled, specifically to determine if any overlapping time periods exist.
- 3.Does the individual's profile only contain controlled substance prescriptions?
- Does the individual ask only for the controlled substance prescriptions to be filled? The individual does not want the non-controlled substances prescribed on the same prescription blank to be filled.
- Prescription drug abusers will often attempt to obtain controlled substances from multiple pharmacies during adjacent or overlapping periods of time. The pharmacies may be located in different communities and can be considerable distances apart.
- An individual may fill their prescriptions near their home, work or prescriber. It is helpful to identify pharmacies that an individual fills
 prescriptions at that are not located near home, work or prescriber and cannot be reasonably explained.
- An individual may ask that only the narcotic be filled because they "have enough of the blood pressure, antibiotic, etc."
- Does the individual pass other pharmacies on the way to your pharmacy?
- In an attempt to avoid detection, prescription drug abusers will often attempt to fill controlled substances from pharmacies outside of their geographical area.
- There are documented cases where drug abusers will travel great distances often across many states to obtain controlled substances for illicit use.

 Prescription drug abusers will often attempt to obtain controlled substances prescriptions from prescribers outside of their geographical area.

5.

- Does the individual use street names when discussing controlled substances (i.e. "Mallinckrodt blues", "M's", "Percs",
 "Reds", "Oxy", "OC", etc.)?
- Is the individual presenting to the pharmacy in an "intoxicated" or "incoherent" state?
- Is behavior exaggerated (e.g., over-friendly and talkative) or very nervous and anxious?
- Is the individual challenging or belligerent when asked additional questions about the prescriptions?
- Inappropriate individual conduct and knowledge of street names can be important indicators of abuse.
- Prescription drug abusers may be reluctant to provide personal information needed to assist the pharmacist in the prescription review and consultation process.

6.

- Is the individual taking the medication properly? Have dosing instructions been changed by prescriber?
- Are DUR edits flagging the prescription as too early to refill?
- Does the individual frequently offer explanations to justify the early refill (i.e. "somebody stole my medication" or "I lost my medication"?)
- Frequent early fills can be an indication of either intentional abuse or unintentional misuse.
- Individual history should be reviewed to identify if an early refill pattern exists. A pattern of early fills can indicate abuse.

7.

- Does one individual drop off and pick up prescriptions for multiple other individuals?
- Does a group of individuals come into the pharmacy with the same prescriptions from the same prescriber?
- Do all the individuals live together and/or are they all related?
- Do multiple narcotic prescriptions come in from the same prescriber following the filling of one prescription for a patient?
- Prescription drug abusers may attempt to use one individual or may travel in groups to obtain controlled substances from pharmacies.
- Prescription drug abusers may use one common address in the attempt to obtain controlled substances from pharmacies.
- When word gets out that one prescription was filled, then many patients come to the same pharmacy from the same prescriber for narcotics.

Prescription Considerations

- 1. Prescriptions presented represent a cocktail of commonly abused drugs.
- 2. Prescriptions presented is for an unusually large quantity or high starting dose.
- 3. Individual insists on the brand name, or a certain generic company's drug being dispensed.
- 4. Prescriptions appear to be altered or duplicated.



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- 1.
- Does a review of the individual profile or state PMP reveal this combination of agents?
- Does the prescriber routinely prescribe this same combination of drugs, in similar strengths, for most individuals?
- The abuse of any combination of the above controlled substances is a trend that has been identified by law enforcement officials.
- The combination of a narcotic, a benzodiazepine, and a muscle relaxant can have a synergistic effect on an individual's central nervous system and cause respiratory depression thus posing a substantial risk to any individual actually taking the drugs as prescribed.
- It has been observed by law enforcement that many prescribers writing for illegitimate purposes will often write prescriptions for the same combination of drugs, usually in the same strength, for all individuals.
- 2.

3.

4.

- Is the quantity and strength of the medication prescribed appropriate for the indication?
- Is the daily dose prescribed higher than the normal daily dose?
- Is the prescriber writing prescription(s) without any consideration of the individual (age, weight, etc.)?
- A large quantity of a medication or an unusually high starting dose for an acute ailment may be an indication that the prescription was not written for a legitimate medical purpose.
- It has been observed that many prescribers writing for an illegitimate medical purpose will write prescriptions for the same dose and duration of therapy no matter the age or weight of the individual.
- What is the individual's rationale for insisting on a particular brand name or generic manufacturer?
- Brand name and certain generic company drugs typically command a higher street value than do other drugs due to the fact that they are
 easily identified by their shape or markings, and are more readily recognizable in and amongst drug abusers involved in illicit drug
 trafficking.
- · Referring to prescription products by their street names is highly indicative of abuse and illegitimate use.
- Does any information in particular the quantity, strength, or refills appear altered on the prescription?
- Is the prescription written in different colors of ink/pencil?
- Does the handwriting differ throughout the prescription?
- Does the prescription look like it has been duplicated by a scanner or copier with a signature added in ink?
- · Prescription drug abusers will attempt to alter prescriptions in order to obtain larger quantities and or refills.
- Any prescription can be altered, but prescriptions from emergency rooms, immediate care centers, and hospitals are typically targeted by drug abusers.



Prescription Selection

Criteria:

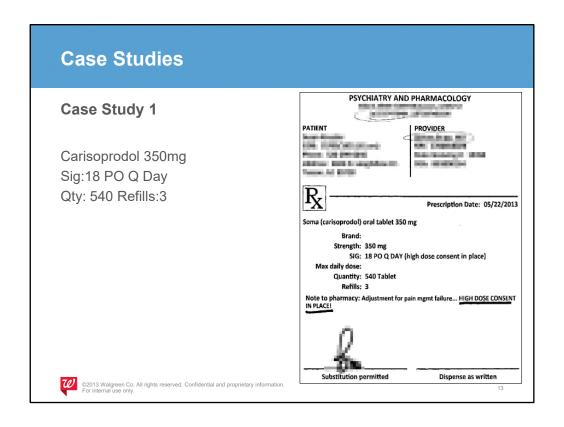
- 1. High dose controlled substance
- 2. High quantity Oxycodone
- 3. High quantity Methadone
- 4. High quantity Hydrocodone
- 5. Cocktails such as an Opiate or Hydrocodone, Benzodiazepine and Carisoprodol
- 6. New patients with a high quantity control substance paying cash



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Specific Criteria to talk to:

- High dose controlled substance three standard deviations above the average dose for that specific drug and strength
- 2. Third Party Oxycodone 15mg and 30mg with quantities greater than 180
- 3. Cash Oxycodone 15mg and 30mg with quantities greater than 120
- 4. Methadone quantities greater than 240
- 5. Hydrocodone quantities greater than 240
- 6. Cocktails identified as an Opiate or Hydrocodone, Benzodiazepine and Carisoprodol, where the Benzodiazepine and Carisoprodol (or Gabapentin) were both dispensed within 12 days plus of the Opiate dispensing date.
- 7. New Patients between the ages of 18-40 that paid cash for any CII or CIII script



Case Studies

Case Study 2

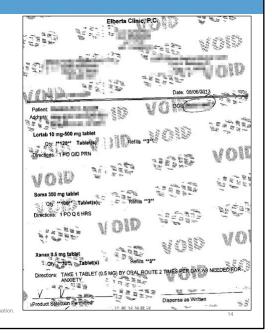
Hydrocodone 10/500mg Sig:1 PO QID PRN Qty:120

Carisoprodol 350mg Sig:1 PO Q 6hrs Qty:100

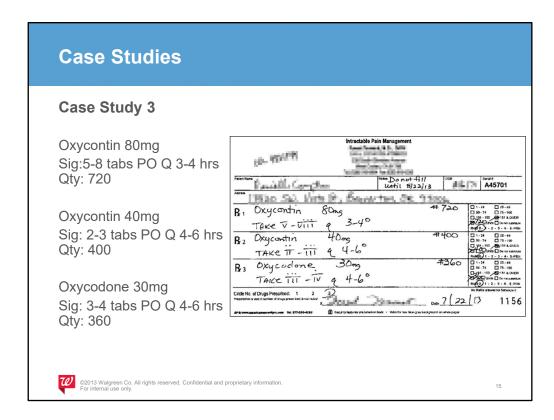
Alprazolam 0.5mg

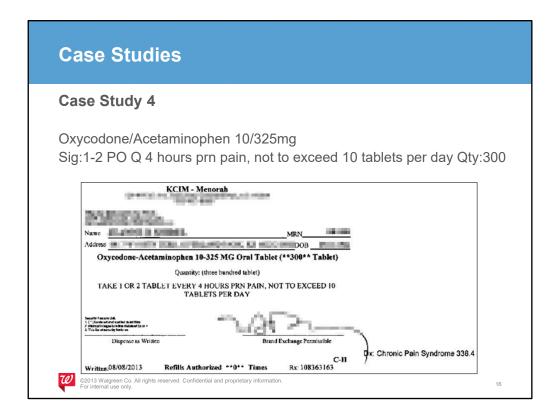
Sig: 1 PO BID PRN for anxiety

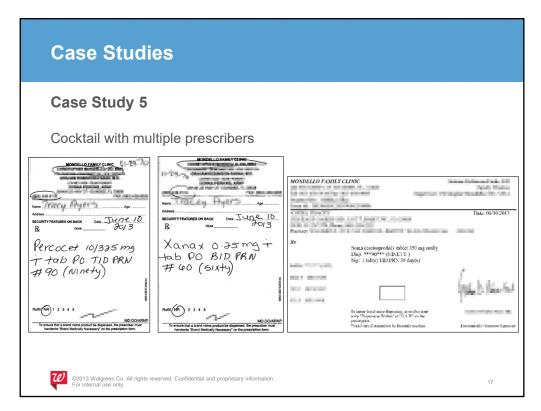
Qty: 30











• Where is the documentation that the cocktail is prescribed by different doctors and all of the doctors are aware that the patient is receiving these medications.

Talking Points

- Not all prescription examples are necessarily bad prescriptions.
- The decision whether to dispense or refuse may vary by pharmacist but should be reasonably explained.
- It's important to look for documentation that the pharmacist used the tools available as appropriate in the decision making process, such as the PDMP, reviewing the patient profile, or speaking with the patient or caregiver.



- Important to note:
 - DEA, Board of Pharmacy, Third Party Auditors use documentation to ensure the validity and actions taken for a prescription

What if a prescription example I review with my pharmacist fits within the guidelines of Good Faith Dispensing?

- District and market leadership store visits reinforce GFD. The Pharmacist GFD Tool was designed to assist leadership in having discussions with pharmacists around good faith dispensing.
- Certain prescription examples may appear to fit within the confines of GFD practice. Look for documentation to support the pharmacist's TD/GFD decision.
- The decision to dispense a prescription is ultimately up to the pharmacist, however, proper documentation to support the decision is needed. It is important that pharmacists document all actions taken during GFD process.



Supporting Documents

- GFD and TD GFD Policy posted on StoreNet
- RX Integrity website, web portal, and CE's located at:
 - StoreNet > Rx Ops > Pharmacy Policies and Procedures > Rx
 Integrity



Next Steps

- Review and familiarize yourselves with:
 - · Resources available on the RX Integrity website
 - Pharmacists identified in your area
 - · Prescription examples specific to your pharmacists
 - Patient, prescriber and prescription considerations
- Incorporate pharmacist coaching on controlled substances in your store visits
- Ensure all stores have a "refused" folder for controlled substances
- · Communicate with your pharmacists



Questions?

- Pharmacy Supervisors can direct questions to the Divisional Rx Integrity
 Managers:
 - Christopher (Chris) Dymon East
 - Patricia (Patty) Daugherty Midwest
 - Edward (Ed) Bratton South
 - Eric Stahmann West

OR

Rx Integrity E-mail: (<u>rxintegrity@walgreens.com</u>)



